PMSD/ISB 2276

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 14 1988

MEMORANDUM

SUBJECT: PP#7F3476/FAP#7H5524. Rally™ (Myclobutanil). Defining The Regulable Residue.
RCB No.: None. MRID No.: None.

FROM: Maxie Jo Nelson, Ph.D., Chemist
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THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
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TO: Lois A. Rossi, PM 21
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and

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Hazard Evaluation Division (TS-769C)

Introduction

On April 11, 1988, TOX (E. Budd, W. Burnam) and RCB (M. Nelson, R. Quick) met to review and discuss the need to regulate bound (conjugated) RH-9090 in the commodities of this petition. RH-9090 is the alcohol metabolite of myclobutanil (RH-3866).

It was agreed there was a need to regulate bound RH-9090 in apples, grapes, their byproducts, and in milk.

It was reconfirmed that parent compound (RH-3866) and free RH-9090 were to be regulated in all the commodities of this petition and that, in milk, the diol metabolite (RH-0294) was also to be regulated.

Rationale Behind the Decision on Bound RH-9090

The plant metabolism studies show that bound RH-9090 can be a significant component of the residue in apples (see Table VII, TR 310-84-31) and grapes (see Tables 6 and 8, TR 310-84-30). The proposed enforcement method for crops (TR 310-84-27) measures total RH-9090 (and parent RH-3866). Apple and grape proposed tolerance levels are 0.5 and 1.0 ppm, respectively.

In eggs and poultry tissues a §180.6(a)(2) situation exists (see Tables 5 and 8, TR 31H-86-16). Only method sensitivity level tolerances for eggs and poultry tissues are thus needed in re this petition (see RCB 2/5/88 review, p. 85). Logic dictates the same components be regulated in poultry tissues and eggs as in the meat, fat, and meat byproducts of other livestock.

In the meat, fat, and meat byproducts (except liver) of livestock other than poultry, RCB has recommended (2/5/88 review, p. 82) a 0.05 ppm tolerance level as being appropriate. Kidney may contain ca 0.03 ppm total residue, and muscle and fat, NDR (figures based on extrapolation from cattle feeding study data, using a dietary burden level of 5.5 ppm; see 2/5/88 RCB review, pp. 80-81). Bound RH-9090 was not identified in kidney (per petitioner's statement, p. 6, MAM 88-19), but has been reported in urine (see TR 31H-86-18, pp. 24-29). Were bound RH-9090 to be in kidney, it would be expected in the aqueous methanol fraction derived from the ethanol-extractable activity; this fraction constituted 23% of the total activity in kidney (see Figure 4, TR 31H-86-18). Bound RH-9090 would thus comprise <0.01 ppm total activity (0.03 ppm x 23%), a level too low to be of TOX concern.

In liver (dairy cattle metabolism/feeding study), the petitioner has now clarified that bound RH-9090 was not observed (p. 7, MAM 88-19). Were any bound RH-9090 to be in liver, it would be expected in the aqueous methanol fraction derived from the ethanol-extractable activity; this fraction constituted only 6.4% of the total activity in liver (see Figure 3, TR 31H-86-18). This low a level (0.011 ppm, based on 0.18 ppm average extrapolated total residue in liver at the dietary burden level of 5.5 ppm x 6.4%) would not be considered of significant enough concern to warrant inclusion in the tolerance expression. The TAS run supports this conclusion re liver (see the 4/5/88 TOX review, p. 3).

In milk, bound RH-9090 (in the form of 4 polar metabolites) comprises a significant portion of the residue (see Tables III, VIII, and IX and p. 29 of TR 31H-86-18). Milk is a staple of the diet of children. (See TAS printouts attached to the TOX review, 4/5/88.) TOX considers bound RH-9090 to be of sufficient toxicological concern to be included in the tolerance

Conclusion

RCB and TOX are in agreement the regulable residue for the commodities of this petition should be as follows:

Commodity	Regulable Residue
Apples, Apple Pomace; Grapes, Grape Pomace; Raisins, Raisin Waste.	RH-3866 RH-9090 (free) RH-9090 (bound)
Milk	RH-3866 RH-9090 (free) RH-9090 (bound) Diol (RH-0294)
Meat, Fat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, Poultry, and Sheep; Eggs.	RH-3866 RH-9090 (free)

NOTE TO PM:

This is not RCB's response to the petitioner's recent amendments to this petition. Those will be addressed by separate memo, and a listing of the deficiencies remaining to be resolved for RCB re this petition will be given at that time.

cc: RF, Circ, Reviewer (Nelson), PP#7F3476/FAP#7H5524, H. Jacoby (SPMS), Myclobutanil Registration Standard File, ISB/PMSD (Eldredge).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):4/12/88.
RDI:SectionHead:RSQuick:4/12/88:DeputyChief:RDSchmitt:4/12/88.